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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/600,546	06/20/2003	Steven E. Baldini	66638-40285	6084
7590	11/01/2005		EXAMINER	
Clyde L. Smith Thompson Coburn LLP One US Bank Plaza St. Louis, MO 63101			STEWART, ALVIN J	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 11/01/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

TAK

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/600,546	BALDINI ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Alvin J. Stewart	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 23 August 2005.  
 2a) This action is FINAL.                  2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 3,5,6 and 9-20 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 3,5,6 and 9-20 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 20 June 2003 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
|  | 6) <input type="checkbox"/> Other: _____                                    |

***Response to Arguments***

Applicant's arguments filed August 23, 2005 have been fully considered but they are not persuasive.

The Examiner still believes that the Machine design reference clearly reads on the previous rejected claims. The claims disclosed below are given their broadest reasonable interpretation. In re Pearson, 181 USPQ 641 (CCPA 1974). For example, the claims read on a step of forming a socket out of physical material, such that the DCL manufacturing technique automatically forms an access opening in the socket that extends into the cavity from the exterior surface. The Machine Design reference clearly discloses an opening extending into the cavity from the exterior surface. This opening is the opening used by the patient to insert the residual limb into the cavity of the socket.

If the Applicant is trying to claim the secondary opening (70) extending laterally from the exterior surface to the cavity of the socket, the Applicant's representative needs to add more structure limitations to the claims in order to distinguish the secondary opening to the primary opening of the prosthetic socket.

Regarding claims 15 & 16 (US 5,432,703 & US 5,376,132), the Examiner is not clear why the Applicant's representative discloses that the Lynch et al and the Caspers references do not read on claims 15 & 16. The Lynch et al reference and the Caspers reference make an exact copy of the patients residual limb contour without any modification, therefore, the inner surface of the prosthetic socket cavity has the same contour as the residual limb without a process of intentionally rectifying the contour of the interior surface.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 3, 6, 9, 10, 12-17 and 19-20 are rejected under 35 U.S.C. 102(b) as being anticipated by document “Selective Laser Sintering Streamlines Prosthesis design” Machine Design, Penton, Inc. Cleveland, US, vol. 65, no. 3, February 12, 1993, page 77, ISSN: 0024-9114.

Machine Design discloses a method of making an implant comprising generating a digital representation of a three dimensional surface contour that depends on a physical surface contour of at least a portion of a residual limb. Generating a digital representation of a socket of the prosthetic limb and forming the socket out of physical material using a digitally controlled layered manufacturing technique.

Claims 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Lynch et al US Patent 5,432,703.

Lynch et al discloses a method of forming a socket comprising positioning a liner (25) on a portion of a residual limb, forming a socket having an exterior surface and a cavity defined by an interior surface such that the interior surface of the socket has a contour that is dependent upon the exterior surface contour of the liner and attaching the socket of the prosthetic limb to the residual limb.

Claims 15, and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Caspers US Patent 5,376,132.

Caspers discloses a method of forming a socket comprising positioning a liner (42) on a portion of a residual limb, forming a socket (110) having an exterior surface and a cavity defined by an interior surface such that the interior surface of the socket has a contour that is dependent upon the exterior surface contour of the liner and attaching the socket of the prosthetic limb to the residual limb.

Regarding lines 10-12 of claim 15, the interior surface of the socket (110) has a contour that is dependent upon the exterior surface contour of the liner (42) because the interior and exterior contour of the liner adjust at the contour of the residual limb. Therefore, if the interior and exterior contour of the liner have the same contour as the residual limb then the interior surface of the socket will have the same contour as the exterior surface contour of the liner.

#### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 5, 11 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over document "Selective Laser Sintering Streamlines Prosthesis design" Machine Design, Penton, Inc. Cleveland, US, vol. 65, no. 3, February 12, 1993, page 77, ISSN: 0024-9114 in view of Lynch et al US Patent 5,432,703.

“Selective Laser...” discloses the invention substantially as claimed. However, “Selective laser....” Does not disclose the step of positioning at least one artifact adjacent the residual limb prior to electronically scanning the exterior contour of the liner.

Clynch et al teaches a step of positioning at least one artifact adjacent the residual limb prior to electronically scanning the exterior surface contour of the liner for the purpose of holding the patient in a standing position.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to hold the patient in a standing position.

### *Conclusion*

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Double-Wall, transtibial prosthetic socket fabricated using Selective Laser Sintering: A case study; JPO 2000; Vol. 12, Num. 3, p97.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

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however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alvin J Stewart whose telephone number is 571-272-4760. The examiner can normally be reached on Monday-Friday 7:00AM-5:30PM(1 Friday B-week off).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*A. Stewart*

**ALVIN J. STEWART  
PRIMARY EXAMINER**

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October 31, 2005.